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DB=USPT,PGPB,JPAB,EPAB,DWPI; PLUR=YES; OP=ADJ

<u>L3</u>	L1 and asthma	2	<u>L3</u>
<u>L2</u>	L1 and ashtma	0	<u>L2</u>
<u>L1</u>	immunoferon or inmunoferon or glycophosphopept\$5	8	<u>L1</u>

END OF SEARCH HISTORY

(FILE 'HOME' ENTERED AT 12:56:49 ON 11 APR 2003)

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT
12:57:01 ON 11 APR 2003

FILE 'REGISTRY' ENTERED AT 12:57:25 ON 11 APR 2003
E "IMMUNOFERON"/CN 25

L1 1 S E3

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT
12:59:01 ON 11 APR 2003

L2 2 S L1

FILE 'CAPLUS, MEDLINE, USPATFULL, EUROPATFULL, PATOSWO' ENTERED AT
13:01:15 ON 11 APR 2003

L3 68 S IMMUNOFERON OR INMUNOFERON OR GLYCOPHOSHOPEP?

L4 3 S L3 AND (ASTHMA OR ALLEGY OR INFLUENZA)

L1 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2003 ACS
RN 365212-33-5 REGISTRY
CN **Immunoferon (9CI)** (CA INDEX NAME)
ENTE Oral immunomodulator; active principle is a glycoconjugate consisting of
Ricinus communis protein and Candida utilis polysaccharide
MF Unspecified
CI MAN
SR CA
LC STN Files: BIOSIS, CA, CAPLUS, TOXCENTER

*** STRUCTURE DIAGRAM IS NOT AVAILABLE ***
2 REFERENCES IN FILE CA (1962 TO DATE)
2 REFERENCES IN FILE CAPLUS (1962 TO DATE)

4 ANSWER 1 OF 3 CAPLUS COPYRIGHT 2003 ACS
 ACCESSION NUMBER: 2000:627968 CAPLUS
 DOCUMENT NUMBER: 133:202992
 TITLE: **Glycophosphopeptical** or Nigella sativa seeds
 for asthma/allergy therapy that targets
 T-lymphocytes and/or eosinophils
 INVENTOR(S): Nassief, Nida Abdul-Ghani
 PATENT ASSIGNEE(S): Al-Jassim, Rawaa, Australia; Al-Kaisi, Ban; James,
 David
 SOURCE: PCT Int. Appl., 28 pp.
 DOCUMENT TYPE: Patent
 LANGUAGE: English
 FAMILY ACC. NUM. COUNT: 1
 PATENT INFORMATION:

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
WO 2000051580	A2	20000908	WO 2000-IB222	20000302
WO 2000051580	A3	20011018		
W: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, AM, AZ, BY, KG, KZ, MD, RU, TJ, TM RW: GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW, AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG				
GB 2348132	A1	20000927	GB 2000-5003	20000301
EP 1242102	A2	20020925	EP 2000-909548	20000302
R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, FI, CY				
US 2002061841	A1	20020523	US 2001-944564	20010904
PRIORITY APPLN. INFO.:			GB 1999-4777	A 19990302
			GB 1999-13341	A 19990608
			WO 2000-IB222	W 20000302

TI **Glycophosphopeptical** or Nigella sativa seeds for **asthma**
 /allergy therapy that targets T-lymphocytes and/or eosinophils
 AB A pharmaceutical compn. for the treatment and/or prophylaxis of diseases
 caused by type I hypersensitivity reactions consisting essentially of
glycophosphopeptical, or pure Nigella Sativa seeds, in a concn.
 which stimulate Th1 lymphocytes and selectively switch-off the
 eosinophilic airway inflammation. A method of treatment of allergy using
 Th1 stimulating agents, to be administered to a mammal such as human in
 need of such treatment in a shot of 5 days only, resulted in significant
 decrease in symptom score started day 3, and in sputum eosinophils by day
 14, followed by long-term clin. remission of a mean of 6 mo. The BCG-like
 Th1 stimulation is also used in treating diseases in which the body
 defensive mechanism is a cell-mediated immunity, including viral
 infections, including **influenza** and common cold, chronic and
 recurrent urinary tract infection, pelvic inflammatory diseases as
 neuroimmune appendicitis, cancer, Crohn's disease and facial palsy.
 ST **glycophosphopeptical** immunostimulant cell mediated immunity;
 allergy T cell eosinophil **glycophosphopeptical** immunostimulant;
asthma T cell eosinophil **glycophosphopeptical**
 immunostimulant
 IT Intestine, disease
 (Crohn's; **glycophosphopeptical** or Nigella sativa seeds for
asthma/allergy therapy targeting t-lymphocytes and/or
 eosinophils)
 IT Immunoglobulins
 RL: BPR (Biological process); BSU (Biological study, unclassified); BIOL
 (Biological study); PROC (Process)

(E, type 1 IgE-mediated hypersensitivity; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Lymphocyte
(activation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Reproductive tract
(adnexitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Eye, disease
(allergic conjunctivitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Nose
(allergic rhinitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Dermatitis
(atopic; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
(capsules; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Immunity
(cell-mediated; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Urticaria
(chronic; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Allergy
Asthma
(diagnosis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Larynx
(edema; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Cytokines
RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); BIOL (Biological study)
(eosinophil chemotactic factor; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Paralysis
(facial palsy; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drugs
(gastrointestinal; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Allergy inhibitors
Anti-inflammatory agents
Antiasthmatics
Antitumor agents
Antiviral agents
Common cold

Drug delivery systems
Eosinophil
Immunostimulants
Influenza
Mycobacterium BCG
(**glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Interferons
RL: BAC (Biological activity or effector, except adverse); BOC (Biological occurrence); BSU (Biological study, unclassified); BIOL (Biological study); OCCU (Occurrence)
(**glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT T cell (lymphocyte)
(helper cell/inducer, TH1; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Allergy
(immediate hypersensitivity; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Respiratory tract
Urinary tract
(infection; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Respiratory tract
(inflammation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Drug delivery systems
(lozenges; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Cell activation
Cell proliferation
(lymphocyte; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Appendix
(neuroimmune appendicitis; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Drug delivery systems
(ointments, creams; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Drug delivery systems
(ointments; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Drug delivery systems
(powders; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Lymphocyte
(proliferation; **glycophosphopeptical** or *Nigella sativa* seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)
IT Tuberculin
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(purified protein deriv.; **glycophosphopeptical** or *Nigella*

sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Nose
 (rhinitis, perennial; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Nigella sativa
 (seeds; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (solns., nasal; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (solns., ophthalmic; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (suspensions; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (syrups; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (tablets; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (topical; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT Drug delivery systems
 (vaginal; **glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

IT 87139-86-4, **Inmunoferon**
RL: BAC (Biological activity or effector, except adverse); BSU (Biological study, unclassified); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
 (**glycophosphopeptical** or Nigella sativa seeds for **asthma**/allergy therapy targeting t-lymphocytes and/or eosinophils)

L4 ANSWER 2 OF 3 MEDLINE

ACCESSION NUMBER: 92377675 MEDLINE

DOCUMENT NUMBER: 92377675 PubMed ID: 1509986

TITLE: [Immunologic clinical evaluation of a biological response modifier, AM3, in the treatment of childhood infectious respiratory pathology].
 Valoracion clinica inmunologica de un modificador de la respuesta biologica, AM3, en el tratamiento de la patologia respiratoria infecciosa infantil.

AUTHOR: Sanchez Palacios A; Garcia Marrero J A; Schamann F

CORPORATE SOURCE: Servicio de Alergologia, Hospital Insular, Las Palmas.

SOURCE: ALLERGOLOGIA ET IMMUNOPATHOLOGIA, (1992 Jan-Feb) 20 (1)
 35-9.
 Journal code: 0370073. ISSN: 0301-0546.

PUB. COUNTRY: Spain

DOCUMENT TYPE: (CLINICAL TRIAL)
 (CONTROLLED CLINICAL TRIAL)
 Journal; Article; (JOURNAL ARTICLE)

LANGUAGE: Spanish
FILE SEGMENT: Priority Journals
ENTRY MONTH: 199209
ENTRY DATE: Entered STN: 19921009
Last Updated on STN: 19980206
Entered Medline: 19920918

AB To assess the immunoclinical effectiveness of a biological response immunomodulator, we used AM3 (**glycophosphopeptide**), a glucomannan polysaccharide extracted from the cell wall of a strain of *Candida utilis*, in 20 children with asthmatic. . . . the intradermal reaction of 5 antigens (Trichophyton, *Candida albicans*, tuberculin, *E. coli* and bacterial antigens). In the treated group, the **immunoferon** (AM3) reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication (table I, II and III)... . . behaved like an immunostimulant, improving the clinical situation and progress in patients with infectious respiratory disorders. We consider that the **immunoferon** constitutes a coadjuvant therapy to bacterial immunotherapy.

CT Check Tags: Human
Antibiotics: TU, therapeutic use
Antitussive Agents: TU, therapeutic use
Asthma: CO, complications
Asthma: TH, therapy
*Biological Response Modifiers: TU, therapeutic use
Bronchial Spasm: CO, complications
Bronchial Spasm: TH, therapy
*Calcium Phosphates: TU, . . .

RN 87139-86-4 (Immunoferon)

L4 ANSWER 3 OF 3 USPATFULL
ACCESSION NUMBER: 2002:119853 USPATFULL
TITLE: **Asthma/allergy therapy that targets**
T-lymphocytes and/or eosinophils
INVENTOR(S): Nassief, Nida Abdul-Ghani, Doha, IRAQ

	NUMBER	KIND	DATE
PATENT INFORMATION:	US 2002061841	A1	20020523
APPLICATION INFO.:	US 2001-944564	A1	20010904 (9)

	NUMBER	DATE
PRIORITY INFORMATION:	GB 1999-4777	19990302
DOCUMENT TYPE:	Utility	
FILE SEGMENT:	APPLICATION	
LEGAL REPRESENTATIVE:	AL-JASSIM, Rawaa, 2578 River Woods Drive, Naperville, IL, 60565	
NUMBER OF CLAIMS:	24	
EXEMPLARY CLAIM:	1	
LINE COUNT:	772	

CAS INDEXING IS AVAILABLE FOR THIS PATENT.

TI **Asthma/allergy therapy that targets T-lymphocytes and/or eosinophils**
AB . . . diseases in which the body defensive mechanism is a Cell Mediated Immunity, including viral infections, as but not limited to **influenza** and common cold, Chronic and recurrent urinary tract infection, pelvic inflammatory diseases as neuroimmune appendicitis, cancer, crohns disease and facial. . .
SUMM . . . generally directed to the fields of medicine and pharmacology, and specifically directed to a pharmaceutical composition for the treatment of **asthma/allergy**, consisting essentially of Glycophosphopeptical, or as an equivalent pure *Nigella sativa* seeds, which is active to stimulate T-helper lymphocytes type 1 therefor selectively switching-off the eosinophilic inflammation, also treating

viral respiratory tract infections (flue & **influenza**), other viral infection, urinary tract infection, pelvic inflammatory diseases in particular neuroimmune appendicitis, cancer, crohns disease and facial palsy.

SUMM [0003] **Asthma** is the epidemic of the new millennium. Despite the increase in our knowledge, the morbidity, mortality and prevalence of **asthma** and other allergic diseases are increasing as shown by WHO statistics. (1)

SUMM [0004] Barnes J December 1999, review the current state of anti-**asthma** therapy, over the past 10 years there have been striking improvement in the treatment of **asthma** largely as a result of the earlier and more widespread use of inhaled corticosteroids. The developments of new treatments for **asthma** has proved difficult, although several immunologic approaches are undergoing preclinical and clinical assessment. Antileukotrienes are the only new class of drugs to treat **asthma** that have been introduced in the past 25 years, but their efficacy is somewhat limited and unpredictable, as compared with. . . .

SUMM was not associated with large reductions in markers of eosinophilic inflammation, bronchovascular permeability, or mucus hypersecretion. Alternative therapies for corticosteroid-dependant **asthma**, such as methotrexate, cyclosporine and oral gold, are problematic and have high incidence of adverse effect. (2)

SUMM accordingly an outstanding need for an effective and convenient means for treating and/or preventing type I IgE-mediated hypersensitivity reactions, including **asthma**, in mammals.

SUMM [0008] **Glycophosphopeptical**: The present inventor has, surprisingly, found that a short-term administration of **Glycophosphopeptical** (Glicofopeptical) to patients suffering from **asthma** is capable of treating and/or preventing **asthma**, **Glycophospeptical** is marketed under the trade names "IMMUNOFERON" and "INMUNOFERON" drug by Industrial Farmaceutica Cantabria, S.A. (Spain), **Glycophospeptical** is a GLUCOMANNAN from Candida utilis to be used as an immunostimulant. . . . and stimulating cell mediated immunity. It is not indicated for the treatment of diseases caused by type I hypersensitivity and **asthma** defined

SUMM of natural killer cells was reversed to near their levels in young healthy adults. These observations help to explain how **glycophosphopeptical** aids in the restoration of natural cellular immunity and its possible application as an adjuvant to bacterial & viral vaccines. . . .

SUMM [0010] **Inmunoferon** enhances the activities of early-type interferon inducers and natural killer cells, although it is not an interferon inducer by itself. . . .

SUMM [0019] The following studies are considered relevant to the relation between *N. sativa* and **asthma** Sayed 1980: The oil is used in the treatment of **asthma**, respiratory oppression and coughs. The active principal, nigellone, has been isolated from the volatile oil fraction and is reported to be useful in the treatment of bronchial **asthma**. (9)

SUMM immunity to tuberculosis by stimulating Cell Mediated Immunity mediated by T lymphocytes (Th1). The relation of BCG vaccination to **asthma** is a debate. BCG has also been used as a therapeutic agent in the treatment of cancer, inducing Cell Mediated. . . .

SUMM [0031] **Asthma** is an inflammatory mediator soup. (21)

SUMM of selectively switch-off the eosinophilic airway inflammation, normalizing serum interferon This can be achieved by using a novel class of **asthma** therapy, which is the subject of this invention. "days" therapy with a BCG-like Th1 stimulation .fwdarw. long term clinical remission

SUMM [0037] The present invention is introducing a new class of anti-allergy/anti-**asthma** therapy that target the pre-inflammatory phase of the allergic reaction being defined by the

SUMM present inventor as "Th1 lymphocytes" and. . .

SUMM [0038] This present invention provides a pharmaceutical composition and treatment of **asthma/allergy**, consisting essentially of **Glycophosphopeptical**, or an equivalent pure *Nigella sativa* seeds, which is active to stimulate T-helper lymphocytes type I therefor selectively switching-off the. . .

SUMM [0039] The present inventor has, surprisingly, provided a method of treatment for patients suffering from **asthma/allergy**, administering **Glycophosphopeptical** to a mammal such as human in need of such treatment a shot of 5 days only, to get a, . . .

SUMM . . . for the treatment and/or prophylaxis of diseases caused by type I IgE-mediated hypersensitivity reaction, such as extrinsic, intrinsic or mixed **asthma**, allergic and perennial rhinitis, allergic conjunctivitis, chronic urticaria, atopic dermatitis, and/or laryngeal oedema, to be administered to a mammal such. . .

SUMM [0043] The present invention is specifically directed to a medicament characterized in that said Th1 stimulating agent comprises **Glycophosphopeptical** in free base form, or a pharmaceutically acceptable salt or hydrate, or any pharmacologically active form.

SUMM [0046] The use of Th1 stimulating agents in the treatment of allergy/ **asthma** is dependent on the fact that interferon is an *in vivo* Eosinophilic Chemotactic Factor, and that serum interferon and Th1. . .

SUMM [0047] The method of treating a chronic **asthma** and allergy using 5 days schedule is based on that the recommended dose of Th1 lymphocytes stimulating agent is sufficient. . .

SUMM . . . a body immune defensive mechanism is Cell Mediated Immunity as viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections.

SUMM . . . Additionally the present invention provide a method of treatment of viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections comprising the administration to a mammal such as a human in need of such. . .

SUMM . . . preferably 5 days for type 1 hypersensitivity reaction, of particular interest but not limited to the chronic corticosteroid-dependent allergy and **asthma**. It provides a steroid saving activity.

SUMM [0057] Manufacturing a pharmaceutical preparation to provide a therapy for mammals including humans for the treatment of **asthma** and allergy, also a Th1 stimulating and Cell Mediated Immunity stimulating remedy for viral diseases urinary tract infection, pelvic inflammatory disease, crohns disease, and facial palsy. Containing the active ingredient **Glycophosphopeptical** or the pure seeds of *Nigella sativa* as an equivalent. May be administered orally as capsules, tablets, slow release preparations, . . .

DETD . . . invention was conceived during October 1993, after an experiment of nature that happened to the inventor. Being sever asthmatic her **asthma** was relieved after certain health incident. As an immunologist she linked the incident with interferon. This is considered as Stage. . . I. Stage II: The discovery that interferon is a potent *in vivo* Eosinophil Chemotactic Factor. Stage III: A marketed drug **immunoferon (glycophosphopeptical)**, indicated for diseases unrelated to type 1 hypersensitivity, was linked with allergy in a novel way (depending on the above). . .

DETD . . . and severity of the allergic condition after an informed consent into the study. Group 1 including 60 patients treated with **immunoferon** Group 2 including 60 patients treated with placebo.

DETD [0060] 1 - Diseases involved include seasonal allergic rhinitis, allergic conjunctivitis, chronic urticaria, **asthma**, and laryngeal edema.

DETD . . . the total dose received and the schedule of therapy were verified to find the best method of treating various allergies. **Glycophosphopeptical** was given in addition to the conventional

DET D therapy. The full course of 15 g total dose, was divided over 5. . . [0062] Alternatively a single dose of 500 mg **glycophosphopeptical**, Single dose of 1000 mg **glycophosphopeptical**, or one day therapy. Any of this treatment can be repeated on need.

DET D [0076] **Asthma**: dyspnoea, wheeze, and cough.

DET D [0078] During the course of **Glycophosphopeptical** treatment, 80% of the treated patients showed a significant decrease in symptom score in the treated group compared to placebo. . . by day 3, reaching maximum in day 7. Such symptomatic improvement is totally unexpected particularly in patients with allergic rhinitis, **asthma** and laryngeal edema.

DET D [0079] Above all, is the observation that a long-term effect for this short-term therapy was noticeable! During **glycophosphopeptical** treatment it was possible to stop all other forms of therapy, including steroids. Hence the present invention is useful as a treatment and/or prevention of allergy and **asthma**.

DET D [0080] Side effects: few are mentioned in the manufacturer's leaflet, **glycophosphopeptical** is not contraindicated for **asthma** or allergy, no other side effects were noticed during this short course of therapy.

DET D [0081] Stage IV: Nine patients age range 36-72 with chronic severe **asthma** of a duration ranging between 1-32 years, all of whom were on a maximal dose of broncodilators (as recommended by maintenance corticosteroids, were chosen on account of poor response to conventional treatment, were treated according to the present invention administering **glycophosphopeptical** orally as in the following design of study:

DET D [0083] Day 1: is the beginning of **glycophosphopeptical** treatment, 1000 mg **glycophosphopeptical** is administered to the patient 8 hourly, for 5 days (total of 15 grams or 30 capsule) over the whole. . .

DET D [0092] Was carried out to assess "the alteration in airway flow and bronchial patency resulting from **glycophosphopeptical** treatment" by measuring changes in FEVI, PEFR, FEF25% (alveolar), FEF50% (small airways), FEF75% (large airways).

DET D [0094] Hypersecretion of heavy mucus or sputum, resulting in mucus-related symptoms, is characteristic of **asthma**. The eosinophil levels in the sputum are generally found to correlate with the severity of the disease. The sputum produced by the patients during the course of **glycophosphopeptical** therapy was consequently observed for changes both at a macroscopic and a microscopic level

DET D [0101] The total number of asthmatic patients treated with **glycophosphopeptical** is: 25 patients in stage III+10 patients in stage IV+20 patients during the year 1999.

DET D [0104] The reduction in symptom score as a result of **glycophosphopeptica** therapy is shown in table 1

TABLE 1

Mean symptom score	Glycophosphopeptical (N = 55)	Placebo (N = 35)
Day 0	34.5	33.2
Day 3	20.5	27.3
Day 7	9.66	29.7
Day 14	5.8. . .	
DET D	[0109] There was a decrease in the percentage of sputum eosinophils with glycophosphopeptical therapy from 80% to less than 10% within the first two weeks of glycophosphopeptical therapy. In addition the use of student t test shows significant decrease in the number of sputum eosinophils after glycophosphopeptical therapy as compared to pre-treatment number.	

DETD [0111] After the end of the course of **glycophosphopeptical** therapy, during which a total of 30 capsules of **glycophosphopeptical** were administered to each subject, no further **glycophosphopeptical** was administered. Over the next 23 months, the subjects' symptoms were regularly assessed on the following criteria:

DETD [0115] Need for traditional forms of **asthma** therapy . . . mild, being manifested only in some shortness of breath, with mild coughing and small amounts of sputum. Traditional forms of **asthma** therapy were required only when the subjects were suffering from colds. At least eight out of the ten subjects were. . . for each subject during the long-term follow up period was on average reduced from several times per month (prior to **glycophosphopeptical** therapy) to 1-3 times per year.

DETD [0119] Conclusion: **Glycophosphopeptical** is an agent that can be used in treating **asthma** of all types and severity, allergic/ perennial rhinitis, and other allergies. This short-term therapy produce Long-term effect

DETD . . . Stage V: is the discovery that *Nigella sativa* (also known as fitch, black cumin, or love-in-the-mist) is an equivalent to **glycophosphopeptical**. The use of the pure seeds of *Nigella sativa* for the preparation of an **asthma** and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with **glycophosphopeptical**.

DETD [0125] In addition *Nigella sativa* and **glycophosphopeptical** are useful in the treatment of facial palsy, possibly because facial palsy is possibly a complication of a viral infection.

CLM What is claimed is:

1. Use of **glycophosphopeptical** for the treatment and/or prophylaxis of allergy/**asthma** for administration to a mammal such as a human in need of such treatment.
2. Use of **glycophosphopeptical** for the preparation of an **asthma**/allergy drug 7 such as extrinsic, intrinsic or mixed **asthma**, allergic and perennial rhinitis, allergic conjunctivitis, chronic urticaria, atopic dermatitis, and/or laryngeal oedema, to be administered to a mammal such. . .
3. A Pharmaceutical composition comprises **glycophosphopeptical**, in any pharmacologically active form at a concentration of the extract which is effective as a Th1 stimulating agent.
- . . . comprising the administration to a mammal such as a human in need of such treatment, of an effective dose of **glycophosphopeptical**.
7. The use of the pure seeds of *Nigella sativa* for the preparation of an **asthma** and allergy agent in a concentration which was found to perform substantially the same function in substantially the same way to obtain substantially the same results as with **glycophosphopeptical**.
14. The manufacture of a diagnostic kit to diagnose allergy and **asthma** and to asses the severity Of the disease, using of a quantitative serum interferon concentration measurement.
- . . . a body immune defensive mechanism is Cell Mediated Immunity as viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections.
18. A method of treatment of viral respiratory tract infections such as, but not limited to **influenza** and common cold, other viral infections comprising the administration to a mammal such as a human in need of such. . .

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